



United States
Department of
Agriculture

April 2, 2003

Marketing and
Regulatory
Programs

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 03-06

Animal and Plant
Health Inspection
Service

Subject: Implementation of the New Center for Veterinary Biologics'
Killed Veterinary Rabies Reference

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics

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Biologics
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The purpose of this notice is to inform interested parties of the implementation of the new Center for Veterinary Biologics' (CVB) Killed Veterinary Rabies Reference. New Reference Lot 99-02 will replace Reference Lot 89-3-1 effective April 14, 2003, for incorporation into the NIH Rabies Test for Potency as stated by CVB Notice No. 02-17.

After considering comments from the manufacturers of rabies vaccines, the CVB will amend the initial dilution of Reference Lot 99-02 after reconstitution to establish equivalency with Reference Lot 89-3-1. When reconstituted as recommended and then diluted 1:7.6, Reference Lot 99-02 will contain 0.7 IU per ml, which is equivalent to the historical mean potency of Reference Lot 89-3-1.

Reference Lot 99-02 is available upon request from the CVB. Please follow the procedures outlined in Veterinary Services Memorandum No. 800.97 for requesting this reagent. If a serial has already been tested with Reference Lot 89-3-1 before April 14, 2003, and subsequent testing is required, that testing may be with Reference Lot 89-3-1. Reference Lot 99-02 may be used prior to April 14, 2003, at the manufacturer's discretion. The reconstitution and initial dilution procedures to be considered the undiluted reference are included in the updated Reference and Reagent sheet supplied with the reagent. The starting dilution of the reference for use in the assay shall be determined by the user to meet the validity requirements as specified in the relevant Code of Federal Regulations and *Supplemental Assay Method for Potency Testing of Inactivated Rabies Vaccine in Mice Using the National Institutes of Health Test* (SAM 308).

In the future, the CVB Killed Veterinary Rabies Reference will be calibrated to contain 1 IU per ml. The CVB is proposing that rabies products be released based on IU per ml or IU per dose when a new Reference Lot replaces Reference Lot 99-02. Release values presently in approved Outlines of Production would need to be modified to report in



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(Voice/TTY/ASCII/Spanish)
1-800-877-8339

IU based on the IU content of the Reference Lot used by the manufacturer at the time of licensure. This modification will eliminate the need to produce equivalent Reference Lots to previous lots.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics